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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/813,950	03/03/1997	MANFRED ASSMUS	583-252-0-FW	4092

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EXAMINER
SELLERS, ROBERT E

ART UNIT	PAPER NUMBER
1712	

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/813,950	ASSMUS ET AL.	
	Examiner	Art Unit	
	Robert Sellers	1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7,9,11,13,15 and 25-28* is/are pending in the application.

4a) Of the above claim(s) *1,3,5,7,9,11,13 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

This is responsive to the Continued Prosecution Application request filed December 26, 2002.

Claims 1, 3, 5, 7, 9, 11, 13 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in Paper No. 12.

The related applications filed April 17, 2003 have been considered but are not within the realm of the instant claims. Application no. 10/239,867 sets forth the presence of from 0.05-5 wt% of glycerol monostearate (page 10, Release agents section, line 4) which is lower than the claimed minimum of 20% by weight.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by the Drugs Made in Germany article by Petereit et al.

Petereit et al. espouses pharmaceutical particles coated with Eudragit® methacrylic acid/methacrylic ester copolymers (deemed to be a suitable species of thermoplastic acrylic plastic according to page 11, lines 3-8 of the specification) and from 25-50% of tabletting excipients such as glycerol monostearate (last IT, lines 9-10).

The claims are directed to medicinal composition prepared by melt-coating which constitutes a product-by-process format.

"If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (*In re Thorpe*, 227 USPQ 964, 966, Federal Circuit 1985 and MPEP § 2113, the "Product-by-Process Claims' section)." "Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product." (*In re Marosi*, 218 USPQ 289, 292, Federal Circuit 1983 and MPEP § 2113, the section entitled 'Once a Product Appearing to be Substantially Identical is Found and a 35 U.S.C. 102/103 Rejection Made, the Burden Shifts to the Applicant to Show an Unobvious Difference').

The prior art product is the same as that claimed considering the same Eudragit® copolymers and glycerol monostearate employed within the same proportion limits.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yajima et al.

Yajima (col. 5, Example 4 ; col. 6, Example 7 and col. 7, Example 13) shows a composition comprising a drug, Eudragit® E and glycerol monostearate whicih is melt-mixed at a temperature of 100°C.

The cited examples show an amount of glycerol monostearate in excess of the claimed range of from 20-50 wt%. The drug is present preferably from 1-60% by weight (col. 2, lines 55-57) and the Eudragit® E is employed in a quantity of from 2-40% by weight (col. 3, lines 7-8).

It would have been obvious to employ the glycerol monostearate of Yajima et al. within the claimed proportion range for low levels of the drug, Eudragit® E along with the required sugar alcohol and basic oxide in order to optimize the distribution of the drug within the complex.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deleuil et al.

Deleuil et al. discloses a pearl form of a pharmaceutical active substance wherein the pharmaceutical is melt-mixed (col. 2, lines 12-20) with glycerol stearate identified by the tradename Precirol (col. 2, line 43) and Eudragit acrylic resins (col. 3, lines 15-19 and 23). The glycerol stearate is exemplified in proportions of 25%, 40% and 50% by weight (cols. 5-6, Table 1, Tests 1-5) without the Eudragit resin.

It would have been obvious to incorporate the Eudragit resin into the exemplified formulations in order to "permit a completely controlled and adjustable dissolution of the pearls (col. 3, lines 16-18)."

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burguiere et al. in view of Mueller et al.

Burguiere et al. sets forth microcapsules consisting of particles of acetylsalicylic acid (col. 4, lines 10-14) coated with a coating agent comprising an insoluble film-forming polymer (P_1) such as Eudragit® RL and/or RS (col. 6, lines 8 and 12) and as much as 20% by weight (col. 5, line 60) of a plasticizer such as glycerol stearate (col. 6, lines 32-35).

The use of the same Eudragit® RL and/or RS and glycerol monostearate in combination with the acetylsalicylic acid produced by a different solution coating process (col. 7, lines 14-21) of Burguiere et al. results in the same product as that claimed based on the product-by-process rationale presented hereinabove.

Even if the product-by-process language is considered, Mueller et al. teaches the melt extrusion at a temperature of from 60° to 150°C (col. 3, lines 16-19) of a pharmaceutical active ingredient with a polymer melt of a poly(meth)acrylate with a glass transition temperature of from –60° to 180°C (col. 2, lines 2-4) along with as much as 30% by weight of conventional pharmaceutical auxiliaries (col. 2, lines 11-12) such as wetting agents or plasticizers (col. 3, lines 5 and 6). Column 1, lines 36-46 teaches the advantage of melt extrusion to avoid the use of solvents, elaborate mixing processes and possible demixing of the components.

Based on the rationale relied upon in the Board of Patent Appeals and Interferences affirmation rendered October 25, 2002 (page 7, last paragraph), it would have been obvious to prepare the acetylsalicylic acid microcapsule particles of Burguiere et al. via the melt extrusion process of Mueller et al. to obtain the benefits mentioned hereinabove.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth et al. in view of Mueller et al.

Staniforth et al. espouses a sustained-release formulation (col. 5, lines 4-15) obtained from an active ingredient, an augmented microcrystalline cellulose, a sustained release carrier such as an aminoalkyl methacrylate copolymer (col. 18, lines 23, 24 and 27) and as much as about 20% by weight (col. 13, lines 37-39) of a surfactant such as glycerol monostearate (col. 11, line 33) and prepared "in any pharmaceutically acceptable manner known to those skilled in the art (col. 21, lines 27-32)."

The use of the equivalent aminoalkyl methacrylate copolymer and the identical glycerol monostearate together with the active ingredient results in the same product as that claimed based on the product-by-process rationale propounded hereinabove.

Even if the product-by-process terminology is taken into account, it would have been obvious to prepare the sustained-release formulation of Staniforth et al. by the melt extrusion procedure of Mueller et al. in order to take advantage of the aforementioned features.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent No. 51-91317, Rudnic et al. and Pollinger et al. in view of Petereit et al., Burguiere et al. and Mueller et al.

Japanese '317 describes pharmaceutical tablets or granules coated with a 2-methyl-5-vinylpyridine/methyl methacrylate copolymer and glycerol monostearate.

Rudnic et al. discusses a pharmaceutical composition (col. 2, lines 43-49) derived from a pharmaceutical agent, a hydrophilic polymer such as Eudragit® (col. 2, lines 57-58) and a hydrophobic or lipophilic matrix present in amounts of as much as 20.0% (col. 4, Example 1, ATMUL 84S) such as glycerol monostearate (col. 2, lines 63-64).

Pollinger et al. is directed to pharmaceutical microcapsules coated (col. 4, lines 26-28) with a blend of a film-forming agent including acrylic acid copolymers (col. 4, lines 47-48) or Eudragit® NE 30 D (col. 5, line 27) combined with glycerol monostearate as a plasticizer (col. 5, lines 49 and 53) or a surface-active substance or wetting agent (col. 5, lines 58 and 64; and col. 6, line 3).

The claimed amount of glycerol monostearate is not recited. Petereit et al. and Burguiere et al. are described hereinabove. It would have been obvious to utilize the glycerol monostearate of Japanese '317, Rudnic et al., and Pollinger et al. within the proportion range of from 25-50% of Petereit et al. in order to impart fast disintegration of the tablets and as much as the 20% of Burguiere et al. in order to optimize the flow properties which are properties endemic to plasticizers.

Mueller et al. is applied in response to the product-by-process language for the same reasons espoused hereinabove.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller et al. in view of Petereit et al. and Burguiere et al.

The references are explained hereinabove. The claimed glycerol monostearate is not recited. It would have been obvious to use the glycerol monostearate of Petereit et al. and Burguiere et al. as the plasticizer or wetting agent of Mueller et al. (col. 2, lines 66-67 and col. 3, lines 5-6) in order to optimize the flow properties.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Petereit patents are directed to pharmaceutical formulations with film-forming acrylic polymers and a glycerol monostearate emulsifier at concentrations lower than the claimed minimum of 20% by weight.

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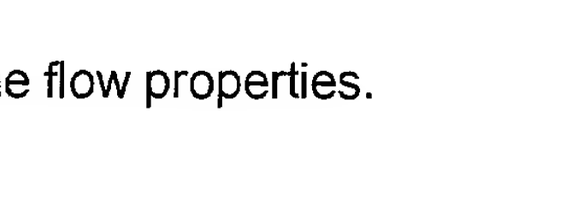

Robert Sellers
Primary Examiner
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10/7/03